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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/811,093
Filing Date: March 16, 2001
Appellant(s): CLENDENNEN ET AL.

Jan P. Brunelle
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 24 May 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

PLEASE NOTE: The top left corner of pages 2-9 of the Appeal Brief states "Application no. 09/846,758". This serial number is not related to the instant application and appears to be a typographical error.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct. Claim 5 is objected to and claims 1, 7, 9-12, 15, and 19-23 were rejected in the final Office action mailed 30 January 2004 and stand appealed.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The Appellants' statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellants' brief includes a statement that claims 1, 7, 9-12, 15, and 19-23 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Aggelis et al., Plant Mol. Biol, 1997, Vol. 33, pages 313-322

Aggelis et al., GenBank Accession No., Z70522, June 2001

Adam et al., Plant Physiol., 1996, Vol. 110, pages 1081-1088

Golden et al., Am. J. Physiol., 1998, Vol. 274, pages L854-L863

Kosugi et al., Nucl. Acids Res., 1991, Vol. 19, page 1571, abstract

Kwon et al., Plant Physiol., 1994, Vol. 105, page 357, abstract

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 7, 9-12, 15, and 19-23 on appeal stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any isolated nucleic acid sequence comprising a promoter operably linked to any heterologous protein-encoding polynucleotide sequence, wherein the promoter consists of any portion of the nucleotide sequence presented as SEQ ID NO: 42 and directs fruit-associated expression of the protein in any plant cell; or any plant expression vector comprising said isolated nucleic acid molecule; or any plant cell comprising said vector; or any mature plant comprising said plant cell; or a method of expressing a heterologous nucleic acid sequence in fruit of any transgenic plant, comprising transforming plant cells with said vector, growing the transformed plant cells to produce a transgenic fruit-bearing plant, wherein the polynucleotide sequence is expressed in fruit.

The specification indicates that the promoter of a gene arbitrarily termed "MEL7" was isolated from cantaloupe fruit. RAP screening was used to isolate an abundant transcript, designated "MEL7," from ripe cantaloupe fruit as part of the process to isolate a DNA fragment comprising the MEL7 promoter from a cantaloupe genomic library (page 25). The MEL7 transcript was relatively fruit-specific and ripening-associated (page 11, lines 28-30). Figures

3A-C present the MEL7 promoter sequence, flanked by vector sequences. The nucleotide sequence shown in Figures 3A-C is also set forth in the 1735 base sequence of SEQ ID NO: 42. The nucleotide sequence that makes up the entire MEL7 promoter, in single-stranded form, in Figures 3A-C is underlined. The numbering in Figures 3A-C is relative to the MEL7 transcriptional start site. Bases 156-1708 of SEQ ID NO: 42 correspond to the underlined portion of Figures 3A-C. A plant expression vector comprising the MEL7 promoter (bases 156-1708 of SEQ ID NO: 42), operably linked to the GUS coding sequence, was introduced into ripe melon fruit by particle bombardment. The MEL7 promoter directed GUS expression in melon fruit in this transient expression assay. The MEL7 promoter also directed GUS expression, using this same transient assay, in transformed fruit tissue of apples, pears, and tomato (page 31, line 5 to page 32, Table 4). Another plant expression vector was constructed in which the MEL7 promoter was operably linked to the coding sequence for S-adenosylmethionine hydrolase (SAMase), and introduced into melon cotyledon tissue explants via Agrobacterium. Transgenic tissues were regenerated into transgenic plants. The MEL7 promoter directed expression of SAMase in fruit of transgenic cantaloupe plants (page 34, line 3 to page 35, line 14). Fruit of transgenic plants showed lower ethylene production versus fruit of non-transgenic control plants (page 35, lines 2-14, Table 9).

A review of the full content of the specification indicates that bases 156-1708 of SEQ ID NO: 42 directs fruit-associated expression of a polynucleotide sequence operably linked to it, and is essential to the operation and function of the claimed invention. A search of the nucleotide sequence set forth in SEQ ID NO: 42 indicates that it is novel and unobvious.

A review of the language of claim 1 indicates that it is drawn to a genus, i.e., isolated nucleic acid molecules comprising a promoter operably linked to a heterologous protein-encoding polynucleotide sequence, wherein the promoter consists of any portion of the nucleotide sequence of SEQ ID NO: 42 that directs fruit-associated expression of the protein. Variation is expected in the nucleic acid molecules, since the portions of SEQ ID NO: 42 that direct fruit-associated expression of the protein can be of any size, and can be from any region of SEQ ID NO: 42. The specification indicates that a fruit-associated promoter is one which directs RNA synthesis at higher levels in fruit cells and tissues (page 7, lines 21-23). Claims 7, 9, and 10 are directed to a plant expression vector comprising the nucleic acid of claim 1. Claim 9 limits claim 7 by indicating that the polynucleotide sequence is operably linked to a control sequence, in addition to the promoter. The specification defines control sequences as transcriptional and translational regulatory nucleic acid sequences (page 7, lines 9-10). Claims 11 and 20 are directed to plant cells comprising the vectors of claims 7 and 10, respectively. Claims 12 and 21-23 are directed to mature plants comprising the plant cell of claim 11. Claims 15 and 19 are directed to a method of expressing a heterologous protein-encoding polynucleotide sequence in fruit of any transgenic plant, which comprises transforming plant cells with the vector of claim 7.

The specification does not describe any portion of SEQ ID NO: 42, other than bases 156-1708, that has fruit-associated promoter activity, and hence the specification does not describe a representative number of the claimed genus of promoter fragments. The specification correlates the function of fruit-associated promoter activity with bases 156-1708 of SEQ ID NO: 42, which is the entire MEL7 promoter sequence, but not to any other fragment of SEQ ID NO: 42.

Nucleotide sequences that are essential to the fruit-associated transcriptional activity of bases 156-1708 of SEQ ID NO: 42 are not described in the specification. The sequences of SEQ ID NO: 42 that must be present within any portion thereof that retains fruit-associated transcriptional activity, other than the sequence of bases 156-1708, have not been described. Portions of SEQ ID NO: 42, other than bases 156-1708, have not been correlated in the specification with any kind of activity. Hence, Appellants fail to describe a representative number of the claimed genus of promoter fragments, or structural features unique to the claimed genus of promoter fragments, in order to satisfy the written description requirement. Given the breadth of the claims encompassing any isolated nucleic acid sequence comprising any portion of SEQ ID NO: 42 that directs fruit-associated expression of a polynucleotide sequence operably linked to it, and the lack of written description as discussed above, it is submitted that the specification fails to provide an adequate written description of the multitude of nucleic acid molecules encompassed by the claims.

Appellant's Arguments and Examiner's Response:

Appellants admit that they have shown only a single genomic fragment of the MEL7 promoter region, nucleotides 156-1708 of SEQ ID NO: 42, as capable of directing fruit-associated transcription of a downstream gene (Appeal Brief, page 3, last full paragraph). Appellants assert that claim 1 encompasses this fragment and subfragments of this genomic fragment that retain the ability to promote fruit-associated expression of the heterologous protein. Appellants argue that the situation is analogous to Example 9 in the Revised Interim Written Description Guidelines Training materials, which presents a claim drawn to a genus of

nucleic acids which must hybridize to SEQ ID NO: 1 and encode a protein with a specific activity. Appellants summarize the conclusions of the example, and argue that in the present case, the claimed genus is much less-encompassing than the genus encompassed by the claim in Example 9 of the Training Materials, because variant sequences that could hybridize under high stringency conditions are not claimed (Appeal Brief, page 3, last full paragraph to page 4, 2nd full paragraph).

However, Example 9 of the Training Materials is not analogous to the instant claim. The claim in Example 9 is directed to a cDNA that encodes a protein product, whereas instant claim 1 is directed to a promoter of a gene. Nucleic acid hybridization methodology using a promoter sequence as a probe is not normally used to isolate promoters of other genes. It is noted that the MEL7 promoter of the instant invention was not isolated by probing cantaloupe genomic DNA with another promoter sequence. While promoters, regardless of tissue specificity, may have consensus sequences such as the TATA box, CAAT box, or GC box, these sequences are not sufficient to alone direct transcription and are not unique to the claimed genus of promoters. The specification fails to provide any information concerning sequences of the MEL7 promoter that are essential to fruit-associated transcriptional activity, and which therefore must be present in all portions of SEQ ID NO: 42 that have fruit-associated transcriptional activity.

Appellants point to Exhibits A-E, provided with the amendment submitted 22 July 2003, as showing that promoter deletion analysis has been routinely used by those skilled in the art to identify subfragments of a promoter sequence that retain promoter activity, and that following the analysis of Example 9 of the Training Materials, claim 1 is supported by adequate written description (Appeal Brief, page 4, 2nd full paragraph).

Exhibit A is GenBank Accession number Z70522, which presents the cDNA sequence of MEL7. Neither the MEL7 promoter nor any other promoter sequences are shown in this reference. Exhibits B-D are abstracts of journal articles. Appellants later submitted the full articles of Exhibits B and C, with the reply received 06 November 2003. Exhibit B is a prior art publication by Adam et al. (Plant Physiol., 1996, Vol. 110, pages 1081-1088). Exhibit C is a prior art publication by Golden et al. (Am. J. Physiol., 1998, Vol. 274, pages L854-L863). Exhibit D is the abstract of Kosugi et al. (Nucl. Acids Res., 1991, Vol. 19, pages 1571-1576), and Exhibit E is the abstract of Kwon et al. (Plant Physiol., 1994, Vol. 105, pages 357-367). The articles and abstracts of Exhibits B-E teach deletion analyses that were performed for various other promoters, and Appellants point to this as a showing that promoter deletion analysis was routine in the art. However, Appellants arguments appear directed to the enablement rejection, not the written description rejection. The routineness of a deletion analysis is not germane to the instant rejection, which considers description of the invention at the time of filing. Further, it is noted that, unlike the instant invention, the references of Exhibits B-E describe multiple fragments of the promoters that retain activity. Furthermore, while Exhibits B-E show examples of promoter deletion analysis, it is established that a method of making a product is not a description of the product itself. See Fiers vs. Sugarno, 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself".

In a telephone interview following the submission of the Appeal Brief, the Examiner proposed to Appellants that claim 1 be amended to indicate that the promoter comprises nucleotides 156-1708 of SEQ ID NO: 42. However, Appellants declined.

Claims 1, 7, 9-12, 15, and 19-23 on appeal stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a portion of SEQ ID NO: 42 consisting of nucleotides 156-1708 that directs fruit-associated transcription, does not reasonably provide enablement for any other portion of SEQ ID NO: 42 as having the functional activity of directing fruit-associated transcription. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any isolated nucleic acid sequence comprising a promoter operably linked to any heterologous protein-encoding polynucleotide sequence, wherein the promoter consists of any portion of the nucleotide sequence presented as SEQ ID NO: 42 and directs fruit-associated expression of the protein in any plant cell; or any plant expression vector comprising said isolated nucleic acid molecule; or any plant cell comprising said vector; or any mature plant comprising said plant cell; or a method of expressing a heterologous nucleic acid sequence in fruit of any transgenic plant, comprising transforming plant cells with said vector, growing the transformed plant cells to produce a transgenic fruit-bearing plant, wherein the polynucleotide sequence is expressed in fruit.

The specification indicates that the promoter of a gene arbitrarily termed "MEL7" was isolated from cantaloupe fruit. RAP screening was used to isolate an abundant transcript, designated "MEL7," from ripe cantaloupe fruit as part of the process to isolate a DNA fragment comprising the MEL7 promoter from a cantaloupe genomic library (page 25). The MEL7 transcript was relatively fruit-specific and ripening-associated (page 11, lines 28-30). Figures 3A-C present the MEL7 promoter sequence, flanked by vector sequences. The nucleotide sequence shown in Figures 3A-C is also set forth in the 1735 base sequence of SEQ ID NO: 42. The nucleotide sequence that makes up the entire MEL7 promoter, in single-stranded form, in Figures 3A-C are underlined. The numbering in Figures 3A-C is relative to the MEL7 transcriptional start site. Bases 156-1708 of SEQ ID NO: 42 correspond to the underlined portion of Figures 3A-C. A plant expression vector comprising the MEL7 promoter (bases 156-1708 of SEQ ID NO: 42), operably linked to the GUS coding sequence, was introduced into ripe melon fruit by particle bombardment. The MEL7 promoter directed expression of GUS in melon fruit in this transient expression assay. The MEL7 promoter also directed GUS expression, using this same transient assay, in transformed fruit tissue of apples, pears, and tomato (page 31, line 5 to page 32, Table 4). Another plant expression vector was constructed in which the MEL7 promoter was operably linked to the coding sequence for S-adenosylmethionine hydrolase (SAMase), and introduced into melon cotyledon tissue explants via Agrobacterium. Transgenic tissues were regenerated into transgenic plants. The MEL7 promoter also directed expression of SAMase in fruit of transgenic cantaloupe plants (page 34, line 3 to page 35, line 14). Fruit of transgenic plants showed lower ethylene production versus fruit of non-transgenic control plants (page 35, lines 2-14, Table 9).

A review of the language of claim 1 indicates that it is drawn to a genus, i.e., isolated nucleic acid molecules comprising a promoter operably linked to a heterologous protein-encoding polynucleotide sequence, wherein the promoter consists of any portion of the nucleotide sequence of SEQ ID NO: 42 that directs fruit-associated expression of the protein. Variation is expected in the nucleic acid molecules, since the portions of SEQ ID NO: 42 that direct fruit-associated expression of the protein can be of any size, and can be from any region of SEQ ID NO: 42. The specification indicates that a fruit-associated promoter is one which directs RNA synthesis at higher levels in fruit cells and tissues (page 7, lines 21-23). Claims 7, 9, and 10 are directed to a plant expression vector comprising the nucleic acid of claim 1. Claim 9 limits claim 7 by indicating that the polynucleotide sequence is operably linked to a control sequence, in addition to the promoter. The specification defines control sequences as transcriptional and translational regulatory nucleic acid sequences (page 7, lines 9-10). Claims 11 and 20 are directed to plant cells comprising the vectors of claims 7 or 10, respectively. Claims 12 and 21-23 are directed to mature plants comprising the plant cell of claim 11. Claims 15 and 19 are directed to a method of expressing a heterologous protein-encoding polynucleotide sequence in fruit of any transgenic plant, which comprises transforming plant cells with the vector of claim 7.

The specification does not provide any guidance as to which fragments of SEQ ID NO: 42, other than nucleotides 156-1708, retain its fruit-associated promoter activity. No information is provided at all concerning the regions of the MEL7 promoter of nucleotides 156-1708 of SEQ ID NO: 42 that are essential to its fruit-associated promoter activity, and which must be present in all portions of SEQ ID NO: 42 that have fruit-associated transcriptional activity. See

Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention. One skilled in the art cannot predict what portions of bases 156-1708 of SEQ ID NO: 42, or other portions of SEQ ID NO: 42, retain this activity. Further, it is noted that only bases 156-1708 of SEQ ID NO: 42 are MEL7 promoter sequences. In the absence of further guidance, one skilled in the art is left to make all possible fragments of all possible sizes and from all possible regions of SEQ ID NO: 42 and test them for retention of activity, which amounts to undue experimentation. As SEQ ID NO: 42 is 1735 bases long, this is not a trivial matter, as the claims encompass portions of SEQ ID NO: 42 of any and all sizes of a nucleotide or more. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

Appellants' Arguments and Examiner's Response:

Appellants argue the Examiner seems to want a disclosure of the precise minimal promoter segment necessary for fruit-associated expression, but that this is not a requirement of the patent law (Appeal Brief, page 5, 1st full paragraph). However, all portions SEQ ID NO: 42 that direct fruit-associated expression must, at the least, contain the minimal promoter sequence within SEQ ID NO: 42 that has this activity. Further, it is unknown whether different, non-overlapping portions of SEQ ID NO: 42 may have fruit-associated transcriptional activity. Given that upstream repressor elements can obliterate promoter activity when present in a

fragment, empirical guidance is necessary to identify those fragments that retain fruit-associated promoter activity and those that do not.

Appellants continue by providing reasons why the Wands factors were not met. Appellants argue that at the time of the invention it was within the capabilities of one of ordinary skill in the art to start with a 1562 nucleotide sequence (note that SEQ ID NO: 42 is actually 1735 nucleotides long) known to have promoter activity and perform a deletion experiment to determine the portion of the sequence responsible for the promoter activity. Applicants again direct attention to Exhibits A-E, submitted with the amendment filed 22 July 2003, in support (Appeal Brief, page 5, 2nd full paragraph).

As discussed above, Exhibit A presents the MEL7 cDNA sequence appearing in GenBank Accession No. Z70522 and does not teach any promoter sequence. Exhibits B-C teach deletion analyses performed for the promoters of the tobacco phytochrome B gene and the human ET-1 gene, respectively. Only the abstracts of the publications of Exhibits D and E were submitted, which indicate that the articles to which they belong discuss deletion analyses of the promoters of the rice PCNA gene and the Arabidopsis thaliana GapB gene, respectively. However, an assay for *finding* a product is not equivalent to a positive recitation of how to make a product. Alternatively, disclosure of a method for producing a product does not reduce to practice the product itself. See *Bayer v. Housey*, Appeal No. 02-1598, (Fed. Cir. 2003), decided 22 August 2003, penultimate page: "processes of identification and generation of data are not steps in the manufacture of a final [drug] product". Further, it is the specification that must teach the enabling aspects of the invention. Genentech, Inc. v. Novo Nordisk, A/S, *supra*.

Appellants point out one statement made by the Examiner in a previous Office action regarding experimentation, and argue that the Examiner implied that the need to conduct any experimentation meant that a claim is not enabled (Appeal Brief, paragraph bridging pages 5-6). The statement pointed out by Appellants appears in the Office action mailed 01 October 2003, on page 6, 1st full paragraph. However, contrary to Appellants' misleading assumption, it was never the Examiner's intention to imply that *any* amount of experimentation would render a claim as not enabled. None of the other Office actions reflect this supposed implication. Indeed, the first full paragraph on page 5 of the Office action mailed 01 October 2003 states that the experimentation required to enable the claimed invention is undue. While the sentence emphasized by Appellants in their arguments does not include the term, "undue," this omission was entirely unintentional. The Examiner realizes and appreciates the importance of the term "undue" in relation to 35 U.S.C. 112, 1st paragraph. However, the omission of this term from the one sentence highlighted by Appellants was only an oversight, as evidenced by its inclusion in other locations of the rejection in the same Office action pointed to by Appellants, and in all of the other Office actions.

Appellants argue that the specification provides the sequence of the promoter region of the MEL7 gene, and Example 4 describes assays for assessing promoter activity in various fruit-bearing plants. Appellants argue that this is sufficient direction should one skilled in the art wish to practice the invention of claim 1 using a promoter fragment from SEQ ID NO: 42 other than the specific embodiment described in the working examples (Appeal Brief, page 6, 1st full paragraph). However, Example 4 provides no guidance at all regarding the portions of the MEL7 promoter that would be expected to retain fruit-associated transcriptional activity. No

suggestion is even provided concerning the size and number of fragments that one skilled in the art should make from the 1735 nucleotide sequence of SEQ ID NO: 42. Appellants argue that Example 2 shows the isolation and characterization of a promoter encompassed by claims 1 and 5 (Appeal Brief, page 6, 2nd full paragraph). This promoter consists of nucleotides 156-1708 of SEQ ID NO: 42, and is the entire MEL7 promoter sequence. Other sequences present in SEQ ID NO: 42 are vector sequences (see Figures 3A-C). Example 2 is a working example of a portion of SEQ ID NO: 42 that directs fruit-associated expression, insofar as the portion comprises the entire MEL7 promoter sequence isolated by the inventors (nucleotides 156-1708 of SEQ ID NO: 42). No working examples of portions of the MEL7 promoter are taught in the specification. Further, the claims encompass not only plant cells, but also any and all mature plants and a method of expressing a heterologous protein in any and all transgenic fruit-bearing plants. This includes any and all fruit-bearing trees. One skilled in the art would need to know not only how to transform cells of any fruit-bearing tree, but also know the tissue culture techniques for any fruit-bearing tree to grow the transformed tissue to produce mature trees, which is not trivial.

Appellants argue that the nature of the claimed invention concerns plant promoters; that at the time of the invention, plant promoters were widely studied and numerous publications were available, for example Exhibits A-E; assert that at the time of the invention, the type of experiments performed to determine whether fragments of a promoter sequence having a known promoter activity retain the same activity were routine and straight-forward to one of ordinary skill in the art; that it is highly predictable that one skilled in the art will be able to make fragments of nucleotides 156-1708 of SEQ ID NO: 42 that retain fruit-associated promoter activity (Appeal Brief, page 6, 3rd–6th full paragraphs). However, in the absence of guidance

concerning regions of the 1552 nucleotide sequence of bases 156-1708 of SEQ ID NO: 42 that are essential to fruit-associated promoter activity, and which must be in every promoter fragment, one skilled in the art is left to make guesses as to the regions of SEQ ID NO: 42 that should be tested, and the sizes of the fragments. Further, as broadly interpreted, the portions of SEQ ID NO: 42 that direct fruit-associated expression that is encompassed by claim 1, need not share any overlapping regions. As the specification does not provide any information concerning the sequences of the MEL7 promoter responsible for the fruit-associated promoter activity, it remains to be determined whether there is only a single minimal sequence within SEQ ID NO: 42 that has this activity.

Finally, Appellants argue that the breadth of the claims is quite narrow, that the only difference amongst the species encompassed by the claimed genus will be the amount of sequence flanking the minimal promoter sequence necessary for fruit-associated promoter activity (Appeal Brief, page 7, 1st full paragraph). However, again, the specification does not teach this minimal promoter sequence. Further, the presence of upstream cis elements can radically alter or obliterate promoter activity such that one cannot reliably predict that all fragments comprising a minimal promoter fragment will have fruit-associated promoter activity. It was also previously suggested to Appellants (in the Office action mailed 01 October 2003) that if other portions of SEQ ID NO: 42 have been determined to direct fruit-associated transcription in plant cells, that a 1.132 declaration be submitted which teaches the portions and that they were determined using the teachings of the specification. However, no such declaration has been received.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Ashwin Mehta
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August 4, 2004

Conferees

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